19. An intramedullary lockable compression screw according to claim 18, further comprising: an aperture in the trailing end of the tubular member, configured to accommodate a tool for applying a torque to the tubular member.

20. An intramedullary lockable compression screw according to claim 19, wherein the aperture in the trailing end of the tubular member, includes: a non-threaded portion configured to accommodate a tool for applying a torque to the tubular member; and a threaded portion configured to engage a tool for extracting the tubular member from a body joint.

REMARKS

Claims 1, 2, 4, 6 and 7 have been amended and claims 11 – 20 have been added. Claims 1 – 20 remain pending in the application. Re-examination of the claims is requested.

Claims 11 and 12 have been added claiming subject matter disclosed in the specification at page 18, lines 3 - 5 and 10 - 11, respectively. No new matter has been added.

Claim 13 has been added claiming the invention with a distal through hole without also requiring the presence of a proximal through hole. Claims 14 – 17 have been added claiming subject matter originally claimed in claims 5 – 8. No new matter has been added.

Claim 18 has been added claiming the subject matter of claims 1, 3 and 4. Claims 19 – 20 have been added claiming subject matter originally claimed in claims 9 and 10. No new matter has been added.

The Examiner has objected to the disclosure because of a typographical error at page 3 lines 3 – 4. The Application has corrected this error. Therefore, the Examiner is respectfully requested to remove this objection.

Claims 1, 2 and 4 – 9 stand rejected under 35 U.S.C. 103 as being unpatentable over Herbert in view of Kim. After briefly characterizing the Herbert invention the Examiner states that "Herbert does not disclose the through-holes." To solve this deficiency, the Examiner cites Kim and after briefly describing some features of the Kim invention concludes that it would have been obvious to combine the Herbert invention with the Kim invention. The Applicant respectfully disagrees. For the reasons given below, it is respectfully submitted that Kim is non-analogous art to the presently claimed invention and even were Kim to be analogous art, the structure resulting from the combination of Herbert and Kim would still be different in structure and function from the presently claimed invention.

The Herbert invention is a bone screw for fastening two pieces of bone together. (Col. 1, lines 5 – 7) Other than a reference to orthopaedic surgery use (col. 2, lines 31 – 32), there is no specific description of the bone or bones that the Herbert bone screw would be used to connect.

The Kim invention is a "compression device for intramedullary system" (Title) and "particularly to an improved rod fixation system for fractures in long bones." (Col. 1, lines 4 – 6, emphasis added) After describing the state of the art of "[f]ractures in long bones" (col. 1, lines 7 – 67), Kim describes the problems with the then existing "intramedullary rod systems." (Col. 2, lines 1 – 12) Kim then concludes:

> "It is therefore desirable to have a long bone fixation device that is simple and more effective than present systems." (Col. 2, lines 36 – 37, emphasis added)

To this end, Kim created "a long bone fixation device" (col. 2, lines 43 – 48, emphasis added), also referred to as "an improved intramedullary rod fixation system for long bones for fixation of bones that have been fractured" (col. 3, lines 19 – 21, emphasis added) "designed to be utilized in any long bone of the body, such as the humerus, femur, tibia and other bones" (col. 3, lines 53 – 55, emphasis added) "to provide a more effective long bone fixation device" (col. 2, lines 41 – 42, emphasis added). There is no teaching or suggestion in Kim to use the Kim invention anywhere other than on fractured long bones. Thus, the problem the Kim invention is intended to solve is to connect long bones that have been fractured. It is therefore respectfully submitted that Kim is non-analagous art to the present invention and should not be combined with Herbert in a '103 rejection.

The determination that a reference is from non-analogous art is two-fold. First, is must be ascertained whether the reference is within the field of the inventor's endeavor. If the reference is not within the field of the inventor's endeavor, it must be determined whether the reference is reasonably pertinent to the particular problems with which the inventor was involved. (In re. GPAC, Inc., 57 F.3d, 1573, 1577, 35 USPQ2d 116, 1120 (Fed. Cir. 1995); In re Wood, 599 F.2d 1032, 1036, 202 USPQ 171, 174 (CCPA 1979))

The present invention "relates generally to the stabilization and reconstruction of deformities of body joints, and more particularly to double-threaded screws used for stabilization and reconstruction of deformities of the ankle and subtalar joints, and which are particularly suitable for stabilization and fusion of the tibiotalar, talocalcaneal, tibiocalcaneal and/or

tibiotalocalcaneal joints." (Page 1, lines 4 - 8, emphasis added) Consistent with this classification, in the Objectives section of the specification, only the following anatomical structures for use of the claimed inventions are described:

> "Accordingly, it is an object of the present invention to provide an improved lockable double-threaded intramedullary compression screw for stabilizing by fusion, a body joint such as the ankle and/or subtalar joint." (Page 5, lines 12 - 14, emphasis added).
>
> "It is a further object of the present invention to provide a more easily installable implant, which can be used to salvage a lower extremity damaged ankle or subtalar joints by stabilizing the joints chosen for fusion." (Page 5, line 19 – page 6, line 1, emphasis added)
>
> "It is a still further object of the present invention to provide a lockable double-threaded intramedullary compression screw which can be locked in place to achieve arthrodesis of the ankle by the insertion of one or more locking screws using palpation or direct vision." (Page 6, lines 2 - 5, emphasis added)

Further, the invention is described in the Summary section as "an intramedullary lockable compression screw is provided for stabilizing a joint in a body." (Page 6, lines 10 -11, emphasis added) In the Preferred Embodiment of the Invention section, the "critical step in the use of the invention" is described as "the creation of the intramedullary canal or cavity across the joints between the bones involved in the fusion." (Page 10, line 12 - 13, emphasis added) The description of the claimed invention and its use is also replete with references to its use across joints. There is no mention, teaching or suggestion whatsoever about using the presently claimed invention on long bones.

This emphasis on creating an invention for stabilizing a joint in a body is reflected in the claims themselves that are directed to "[a]n intramedullary lockable compression screw for stabilizing a joint in a body ... ." (Preamble to claims 1, 13 and 18, emphasis added).

In view of the foregoing, the field of the inventor's endeavor is to "stabilize a joint in a body." By definition, a joint includes at least two separate bones. In contrast, Kim's invention is directed to a device to fix long bone fractures. These fractures occur in a single bone that has, of course, been fractured. Other than the fact that bones occur as the work area in both the Kim reference and the current invention, there is nothing else in common between the two inventions. One looking for a solution to connecting two separate bones of a joint would not be motivated to look at art that teaches how to repair a single broken long bone. As a result, it is respectfully submitted that the invention of Kim is not in the field of the inventor's endeavor.

Since the Kim invention is not in the inventor's field of endeavor, the next step is ascertaining whether Kim is reasonably pertinent to the particular problems with which the inventor was involved. . The problem to be solved is always relevant to a determination of patentability. *In re Wright,* 866 F.2d 422 (Fed. Cir. 1989)

As explained in the Background of the Invention section of the specification, a problem the Applicant was trying to solve is allowing a repaired ankle or subtalar joint to be weight bearing while fusion in the repaired joint is achieved. (Page 2, lines 6 – 11) As also explained in the Objectives section of the specification, problems the Applicant was trying to solve are:

> "to provide an improved lockable double-threaded intramedullary compression screw for stabilizing by fusion, a body joint such as the ankle and/or subtalar joint." (Page 5, lines 12 - 14, emphasis added)

> "to provide a lockable double-threaded intramedullary compression screw which can be locked in place by one or more locking screws without the use of an aiming jigs or other alignment device to insert a locking screw(s)." (Page 5, lines 15 – 18, emphasis added)
>
> "to provide a more easily installable implant, which can be used to salvage a lower extremity damaged ankle or subtalar joints by stabilizing the joints chosen for fusion." (Page 5, line 19 – page 6 line 1, emphasis added)
>
> "to provide a lockable double-threaded intramedullary compression screw which can be locked in place to achieve arthrodesis of the ankle by the insertion of one or more locking screws using palpation or direct vision." (Page 6, lines 2 – 5, emphasis added)

Regarding the use of intramedullary nails such as the Kim device, the present application teaches against using such devices as follows:

> "Recently, a technique using intramedullary nails has become popular. However, conventional nails require the use of elaborate jigs to precisely insert locking screws through the small holes in the nails, and thereby lock the nail in place." (Page 2, lines 18 – 20, emphasis added)

The use of elaborate jigs is precisely one of the problems that the present invention is intended to avoid. Consequently, one seeking to solve the problem of eliminating elaborate jigs would not look to intramedullary nails such as the Kim device which require such elaborate jigs.

Regarding the desire to allow a repaired ankle or subtalar joint to be weight bearing while fusion in the repaired joint is achieved, the specification itself teaches the following with respect to intramedullary nails:

> "This is unfortunate because, although the use of intramedullary nails allows a weight bearing load to be placed on the involved joint prior to fusion being achieved, the installation procedure for is much more difficult than the procedure required by traditional techniques. .... At present, the intramedullary nails used for

> ankle fusion, even with interlocking screws, do not bind well in the calcaneus. Therefore, early weight bearing with these nails is not wise." (Page 3, lines 1 – 5 and page 5, lines 1 – 2)

As a result, one looking to allow a repaired ankle or subtalar joint to be weight bearing while fusion in the repaired joint is achieved would not look to intremedullary nails such as the Kim device since intramedullary nails do not bind will in the calcaneus tissue of such joints

In view of the foregoing, it is respectfully submitted that the Kim invention is *not* reasonably pertinent to the particular problems with which the inventor was involved. Therefore, Kim also fails the second part of the analogous art test. As a result, it appears that Kim is not analogous art and should not be combined with Herbert as part of a '103 rejection. The Examiner is respectfully requested to remove his '103 rejection based on the combination of Herbert and Kim and allow the claims.

Claim 4 claims, in part,

> "another through-hole configured to accommodate another locking screw, extending along a straight third longitudinal axis between a third opening, in a third area of the outer periphery of the tubular member, and a fourth opening, in a fourth area of the outer periphery of the tubular member, the third and the fourth areas being proximate to the leading end of the tubular member, with the third longitudinal axis intersecting the first longitudinal axis."

The Examiner has correctly observed that Herbert "does not disclose the through-holes." As a result, the Examiner has looked to Kim for a device having through-holes. Even arguing *arguendo* that Kim is analogous art, the structure disclosed in Kim does not anticipate nor render obvious the subject matter claimed in claim 4. Claim 4 requires:

> "another through-hole ... extending along a straight third longitudinal axis between a third opening, in a third area ... and a fourth opening, in a fourth area ... the third and the fourth areas being proximate to the leading end of the tubular member."

The corresponding structure in Kim, to the degree that there is correspondence between an intramedullary nail and a compression screw, appears to be the hole 24. However, hole 24 includes a cam 26. There is no teaching or suggestion in Kim to create a distal through-hole that does not include a cam 26. This cam 26 is described as "formed by a sloping surface surrounding the hold [sic] or bore 24" (col. 3, lines 45 – 46) and "[s]urrounding the rod is a sloping cam shoulder 26 which forms a wedge-like cam sloping inward in the longitudinally upward direction, or toward the head of the rod or pin" (col. 3, line 65 – col. 4, line 1). Further, cam 26 is described as "cooperat[ing] with a shoulder on a specially constructed lag screw 28 for applying compression to a fracture between two portions of a fractured bone." (Col. 3, lines 41 – 45)

In the presently claimed invention, there is no hole including a cam with a sloping surface to receive a "specially constructed lag screw" which is the only structure disclosed in Kim for such a distally located hole. As a result, it is respectfully submitted that even were the Kim device combined with Herbert there would still not be taught or suggested a hole such as is claimed in the presently claimed claim 4. Consequently, it is respectfully submitted that claim 4 is patentable over the cited art. Claims 13 and 18 also contain similar claim limitation language that that contained in claim 4. For the reasons give above with respect to claim 4, it is respectfully submitted that these claims are also in condition for allowance. Therefore, the Examiner is respectfully requested to examine and thereafter allow these claims.

The Chapman et al. and Bowman et al. patents do not cure the deficiencies of Kim. Chapman et al. teaches a "locking tab member 14 ... provided with two locking tab apertures 30." (Col. 5, lines 22 – 23) The locking tab member 14 and locking tab apertures 30 are themselves "configured and dimensioned so as to allow for passage of a single straight locking tab screw through either of locking tab apertures 30 to secure the locking tab member to a predetermined portion of the tibia." (Col. 3, lines 24 – 29) For analysis purposes, it appears that the Examiner is equating the body member 12 and locking tab member 14 of Chapman et al. with the elongated tubular member and sleeve portion, respectively, of the presently claimed invention. There is no teaching or suggestion for the "body member 12" to itself have a through hole which the locking tab member 14 guides a locking screw into as is required by claim 3. Because there is no teaching or suggestion to do what the Applicant has done in claim 3, it is respectfully submitted that claims 3 is patentable over the cited art.

Bowman et al. teaches a bone screw with threads along its entire length. The proximal end of the Bowman et al. device

> "is fitted with an engaging means 27 to enable threading into a desired material by the bone screw 10. Diverse embodiments of an engaging means 27 are suitable for this purpose, including square or hexagonal cavities in the bone screw head 22, unitary or multiple narrow slots, or grooved cylindrical cavities. The only necessary limitation on the engaging means 27 is that clear passage to the cannula 20 by a guide pin 12 is not impaired. A plan view of bone screw head 22 with the engaging means 27 is shown in FIG. 4. Additionally, threads (not shown) could be formed in the cannula 20 to permit an extraction tool (not shown) to engage these threads to permit easy extraction of the screw 10." Col. 3, lines 26 – 39)

No description or drawing of the "threads (not shown)" are disclosed in Bowman et al. Consequently, it is not apparent what these threads would be and how they "could be formed in

the cannula 20 to permit an extraction tool (not shown) to engage these threads." Since there is no actual disclosure of structure but instead merely a disclosure of a desired result, it appears that Bowman et al. does not teach or suggest the subject matter of claim 10 which claims actual structure disclosed in the specification. Consequently, it is respectfully submitted that claim 10 is patentable over the cited references.

None of the cited references, singly or in combination, teach or suggest what the Applicant has done. Therefore, the cited references to not anticipate or suggest the claimed invention of claims 1, 13 and 18. Because claims 2 - 12, 14 – 17 and 19 – 20 depend from and further limit what is believed to be allowable independent claims, it is respectfully submitted that claims 2 - 12, 14 – 17 and 19 – 20 are also in condition for allowance. Further, for the reasons give above it is respectfully submitted that claims 3, 4 and 10 are patentable on their own merits.

In view of the foregoing, it is respectfully submitted that claims 1 – 20 are in condition for allowance. The Examiner is requested to re-examine claims 1 – 10 and examine claims 11 – 20 and thereafter allow the claims. Should the Examiner find it useful, the Examiner is requested to contact the undersigned at (651) 484-1032 with any questions or comments he may have.

Respectfully submitted,

Applicant

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Clean Copy of the Current Claims as Amended

Claim 1. (Currently Amended) An intramedullary lockable compression screw for stabilizing a joint in a body, comprising: an elongated tubular member extending along a substantially straight first longitudinal axis between a leading end and a trailing end, and including (i) a threaded leading end portion of a first diameter disposed proximate to the leading end, (ii) a threaded trailing end portion of a second diameter, larger than the first diameter, disposed proximate to the trailing end, and (iii) an unthreaded shaft portion interconnecting the threaded leading end and the threaded trailing end portions; a proximal through-hole configured to accommodate a locking screw, extending along a straight second longitudinal axis between a first opening, in a first area of an outer periphery of the tubular member proximate to the trailing end, and a second opening, in a second area of the outer periphery of the tubular member distal to the trailing end, with the second longitudinal axis intersecting the first longitudinal axis at an angle of other than 90 degrees.

Claim 2. (Currently Amended) An intramedullary lockable compression screw according to claim 1, wherein the proximal through-hole is adapted to accommodate a 4 mm locking screw.

Claim 3. (Original) An intramedullary lockable compression screw according to claim 1, wherein: the elongated tubular member has a sleeve portion extending from the trailing end, away from the leading end; and the sleeve portion is aligned with the through-hole and configured to guide the locking screw into the first opening.

Claim 4. (Currently Amended) An intramedullary lockable compression screw according to claim 1, further comprising: a distal through-hole configured to accommodate another locking screw, extending along a straight third longitudinal axis between a third opening, in a third area of the outer periphery of the tubular member, and a fourth opening, in a fourth area of the outer periphery of the tubular member, the third and the fourth areas being proximate to the leading end of the tubular member, with the third longitudinal axis intersecting the first longitudinal axis.

Claim 5. (Original) An intramedullary lockable compression screw according to claim 4, wherein the third longitudinal axis intersects the first longitudinal axis at a 90 degree angle.

Claim 6. (Currently Amended) An intramedullary lockable compression screw according to claim 4, wherein the distal through-hole is adapted to accommodate a 4 mm locking screw.

Claim 7. (Currently Amended) An intramedullary lockable compression screw according to claim 4, wherein a cross section of the distal through-hole, taken along the third longitudinal axis, has a first dimension in a direction parallel to the first longitudinal axis and a second dimension, smaller than the first dimension, in direction perpendicular to the first longitudinal axis.

Claim 8. (Original) An intramedullary lockable compression screw according to claim 7,

wherein the first dimension is approximately 1 inch.

Claim 9. (Original) An intramedullary lockable compression screw according to claim 1, further comprising: an aperture in the trailing end of the tubular member, configured to accommodate a tool for applying a torque to the tubular member.

Claim 10. (Original) An intramedullary lockable compression screw according to claim 9, wherein the aperture in the trailing end of the tubular member, includes: a non-threaded portion configured to accommodate a tool for applying a torque to the tubular member; and a threaded portion configured to engage a tool for extracting the tubular member from a body joint.

Claim 11. (New) An intramedullary lockable compression screw according to claim 1, further comprising a locking screw capable of being passed over a guide wire into the proximal through hole.

Claim 12. (New) An intramedullary lockable compression screw according to claim 4, further comprising a locking screw capable of being passed over a guide wire into the distal through hole.

Claim 13. (New) An intramedullary lockable compression screw for stabilizing a joint in a body, comprising: an elongated tubular member extending along a substantially straight first

longitudinal axis between a leading end and a trailing end, and including (i) a threaded leading end portion of a first diameter disposed proximate to the leading end, (ii) a threaded trailing end portion of a second diameter, larger than the first diameter, disposed proximate to the trailing end, and (iii) an unthreaded shaft portion interconnecting the threaded leading end and the threaded trailing end portions; and a distal through-hole configured to accommodate a locking screw, extending along a straight second longitudinal axis between a first opening in a first area of the outer periphery of the tubular member, and a second opening, in a second area of the outer periphery of the tubular member, the first and the second areas being proximate to the leading end of the tubular member, with the second longitudinal axis intersecting the first longitudinal axis.

Claim 14. (New) An intramedullary lockable compression screw according to claim 13, wherein the third longitudinal axis intersects the first longitudinal axis at a 90 degree angle.

Claim 15. (New) An intramedullary lockable compression screw according to claim 13, wherein the distal through-hole is adapted to accommodate a 4 mm locking screw.

Claim 16. (New) An intramedullary lockable compression screw according to claim 13, wherein a cross section of the distal through-hole, taken along the third longitudinal axis, has a first dimension in a direction parallel to the first longitudinal axis and a second dimension, smaller than the first dimension, in direction perpendicular to the first longitudinal axis.

Claim 17. (New) An intramedullary lockable compression screw according to claim 16, wherein the first dimension is approximately 1 inch.

Claim 18. (New) An intramedullary lockable compression screw for stabilizing a joint in a body, comprising: an elongated tubular member extending along a substantially straight first longitudinal axis between a leading end and a trailing end, and including (i) a threaded leading end portion of a first diameter disposed proximate to the leading end, (ii) a threaded trailing end portion of a second diameter, larger than the first diameter, disposed proximate to the trailing end, and (iii) an unthreaded shaft portion interconnecting the threaded leading end and the threaded trailing end portions; and a proximal through-hole configured to accommodate a locking screw, extending along a straight second longitudinal axis between a first opening, in a first area of an outer periphery of the tubular member proximate to the trailing end, and a second opening, in a second area of the outer periphery of the tubular member distal to the trailing end, with the second longitudinal axis intersecting the first longitudinal axis at an angle of other than 90 degrees and a distal through-hole configured to accommodate another locking screw, extending along a straight third longitudinal axis between a third opening, in a third area of the outer periphery of the tubular member, and a fourth opening, in a fourth area of the outer periphery of the tubular member, the third and the fourth areas being proximate to the leading end of the tubular member, with the third longitudinal axis intersecting the first longitudinal axis wherein the elongated tubular member has a sleeve portion extending from the trailing end, away

from the leading end; and the sleeve portion is aligned with the through-hole and configured to guide the locking screw into the first opening.

Claim 19. (New) An intramedullary lockable compression screw according to claim 18, further comprising: an aperture in the trailing end of the tubular member, configured to accommodate a tool for applying a torque to the tubular member.

Claim 20. (New) An intramedullary lockable compression screw according to claim 19, wherein the aperture in the trailing end of the tubular member, includes: a non-threaded portion configured to accommodate a tool for applying a torque to the tubular member; and a threaded portion configured to engage a tool for extracting the tubular member from a body joint.